



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

MAR 29 2000

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Sanford J. Lewis, Attorney  
P.O. Box 79225  
Waverly, Maine 02170

RE: 99P-2077/CP

Dear Mr. Lewis:

This is an additional interim response to the citizen petition you submitted to the Food and Drug Administration (FDA) on behalf of Health Care Without Harm (HCWH). In the petition you requested that FDA (1) initiate a rulemaking or issue a guidance requiring that all polyvinyl chloride (PVC) medical devices that leach phthalate plasticizers include a prominent, clearly worded warning label as to the potential for di-ethylhexyl phthalate (DEPH) or other phthalate plasticizers to leach out the PVC and to enter the body, potentially causing detrimental health effects, and (2) establish a program to expedite the development and usage of substitutes for PVC medical devices that leach phthalate plasticizers.

In our last response we informed you that we were conducting a risk assessment of the primary phthalate plasticizer (DEPH) used in medical devices and expected it to be completed by January 2000. We have completed a draft of a very exhaustive analysis; because of the complexity and extent of the analysis, we anticipate that Agency review will take several additional months. Upon completion of our review, we will determine our course of action regarding the actions requested in your petition.

If you have questions, please contact Melvin E. Stratmeyer at 301-443-7130.

Sincerely yours,

Linda S. Kahan  
Deputy Director for Relations and Policy  
Center for Devices and Radiological Health

99P-2077

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cc: HFZ-1 (per his request)  
HFZ-2 (Kahan)  
HFZ-215 (JWade, file)  
HFZ-110 (MStratmeyer)  
HFA-305

Drafted:3/22/00:JWade

Review:3/23/00:JSheehan

Revised:3/23/00:MStratmeyer